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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,546	03/20/2001	Karl Kolter	51284	9100
26474	7590	12/22/2005	EXAMINER	
NOVAK DRUCE DELUCA & QUIGG, LLP 1300 EYE STREET NW SUITE 400 EAST WASHINGTON, DC 20005			SILVERMAN, ERIC E	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/811,546	KOLTER ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-19 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-19, and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant is advised that the Examiner assigned to this case has changed. The Examiner currently assigned to this case is **Eric Silverman, PhD**, whose contact information appears at the end of this action. Applicant is also advised that the Art Unit to which this case is assigned has changed. This case is currently assigned to **Art Unit 1615**.

Receipt of Amendment, and Remarks and Arguments filed therewith, filed 10/21/05, is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In light of the amendment, the rejection of claims 1, 3 – 19, and 21 – 24 under 35 U.S.C. 112, first paragraph, are withdrawn.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3 – 19, and 21 – 24 **remain** rejected under 35 U.S.C. 102(b) as being anticipated by Kolter et al., DE 197 09 663 A1, wherein US 6,066,334 is relied upon as the English translation of Kolter, for reasons of record.

Response to Arguments

Applicants arguments have been considered, but are not persuasive. Applicants argue that US 6,066,334 does not disclose a composition with the same time-release properties as that of instant invention. Nonetheless, the components of instant claims are all present in the dosage form of Kolter in amounts commensurate with that of instant claims. A product and its properties are not deemed to be separable, accordingly, the property of delayed release, as recited in instant claims, is not afforded patentable weight. Furthermore, the recitation of "delayed release" is in the claim's preamble. MPEP 2111.02 states "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Instant claims are drawn to a composition. The recitation of "delayed release" in the preamble is a recitation of a property of the composition, and since the body of the claim fully sets forth all of the limitations of the claimed composition, since the body sets forth all of the ingredients of the composition. Applicant further argues that the dosage form of Kolter was formulated in such a way as to impart different release properties than those of instant invention. Examiner suggests that Applicant may be able to overcome this rejection by including limitations in the claims that recite the features of instant formulation that impart the release properties of instant invention, which Applicant claims is different from that of Kolter. If the formulation of Kolter does indeed have different release properties than

that of instant Application, then the features which cause the release properties of instant invention are not likely to be present in Kolter, and limiting the claims according to these features would likely distinguish them over Kolter.

Examiner notes that some of the text of the attachment "Oral Controlled Release Products", especially on page 194, is not legible due to poor print or copy quality. Examiner has nonetheless considered this document as fully as possible.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3 – 19, and 21 – 24 **remain** rejected under U.S.C. 103(a) as being unpatentable over Kolter et al., in view of Ortega U.S. 4,837,032 for reasons of record.

Response to Arguments

Applicant's arguments have been fully considered, but are not persuasive.

Applicant argues that 4,837,034 does not teach or suggest a formulated mixture. However, 4,837,034 is clearly directed to tablets which contain a mixture of many ingredients, which a person of ordinary skill in the art would consider to be a formulated mixture. Applicant further argues that it would not be reasonable to expect the artisan to recognize that using increased amounts of a binder disclosed in 6,066,334 would

lead to the delayed release effects of 4,837,032. However, 6,066,334 shows the use of a binder resulting in a faster release, and 4,837,032 shows that increasing the amount of the same binder results in a slower release profile. Accordingly, the artisan would interpret these results to mean that the release profile would be expected to become slower as the amount of the binder is increased. Applicant additionally argues that the release pattern of the instant invention is due not only to the presence of the polyvinyl acetate/polyvinyl pyrrolidone binder, but to the overall formulation. Accordingly, Examiner suggests that Applicant include limitations in the claims that point out the features of the instant invention that are responsible for the release profile, in order to help distinguish the claimed invention over the prior art.

Conclusion

No claims are allowed. No claims are free of the prior art.

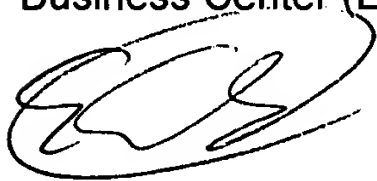
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric E. Silverman, PhD
Art Unit 1615



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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